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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Bernard E. Cabana et al. Art Unit: 1614
Serial No.: 10/668,792 Examiner:
Filed: September 23, 2003 Customer No.: 21559
Title: RIFALAZIL COMPOSITIONS AND THERAPEUTIC REGIMENS

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Applicants submit the references listed on the enclosed Form PTO-1449, copies of which are enclosed.

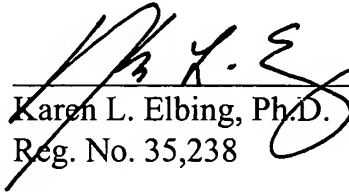
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This statement is being filed before the receipt of a first Office action on the merits.

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Respectfully submitted,

Date: 28 June 2004



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SUBSTITUTE FORM PTO-1449
(MODIFIED)U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICEINFORMATION DISCLOSURE
STATEMENT BY APPLICANT
(Use several sheets if necessary)

(37 C.F.R. § 1.98(b))

Attorney Docket No.

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U.S. PATENTS

Examiner's Initials	Patent Number	Issue Date	Patentee	Class	Subclass	Filing Date (If Appropriate)
	4,983,602	01/08/91	Yamane et al.			
	5,547,683	08/20/96	Yano et al.			
	5,786,349	07/28/98	Yamashita et al.			
	5,981,522	11/09/99	Yamashita et al.			
	6,316,433	11/13/01	Rose et al.			
	6,486,161	11/26/02	Fujii et al.			
	6,566,354	05/20/03	Rose et al.			

U.S. PUBLISHED PATENT APPLICATION

Examiner's Initials	Publication Number	Publication Date	Patentee	Class	Subclass	Filing Date (If Appropriate)
	20030203903	10/30/03	Rose et al.			
	20040034021	02/19/04	Michaelis et al.			
	20040077533	04/22/04	Chalom B. Sayada			
	20040106590	06/03/04	Barry Eisenstein			

FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION

Examiner's Initials	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation (Yes/No)

OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION)

	Bermudez et al., "Activity of KRM 1648 Alone or in Combination with Ethambutol or Clarithromycin Against Mycobacterium Avium in Beige Mouse Model of Disseminated Infection," <i>Antimicrobial Agents and Chemotherapy</i> 38(8):1844 (1994).
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EXAMINER

DATE CONSIDERED

EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with the next communication to applicant.

SUBSTITUTE FORM PTO-1449 (MODIFIED) INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary) (37 C.F.R. § 1.98(b))	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	Attorney Docket No. Serial No. Applicant Filing Date Group IDS Filed Customer No.	50150/064001 10/668,792 Bernard E. Cabana et al. September 23, 2003 1614 June 28, 2004 21559		
		OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION)			
	Dietze et al., "Safety and Bactericidal Activity of Rifalazil in Patients with Pulmonary Tuberculosis," <i>Antimicrobial Agents and Chemotherapy</i> 45(7):1972 (2001).				
	Dhople AM, "In Vivo Susceptibility of Mycobacterium Ulcerans to KRM-1648, A New Benzoxazinorifamycin, in Comparison with Rifampicin," <i>Arzneimittelforschung</i> 51(6):501 (2001).				
	Emori et al., "Evaluation of in Vivo Therapeutic Efficacy of a New Benzoxazinorifamycin, KRM-1648, in SCID Mouse Model for Disseminated Mycobacterium Avium Complex Infection," <i>International Journal of Antimicrobial Agents</i> 10(1):59 (1998).				
	Fujii et al., "In Vitro and In Vivo Antibacterial Activities of KRM-1648 and KRM-1657, New Rifamycin Derivatives," <i>Antimicrobial Agents and Chemotherapy</i> 38:1118, (1994).				
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	Heep et al., "Detection of Rifabutin Resistance and Association of rpoB Mutation S with Resistance to Four Rifamycin Derivatives in Helicobacter Pylori," <i>European Journal of Clinical Microbiology & Infectious Diseases</i> 21:143 (2002).				
	Hirata et al., "In Vitro and In Vivo Activities of the Benzoxazinorifamycin KRM-1648 Against Mycobacterium Tuberculosis," <i>Antimicrobial Agents and Chemotherapy</i> 39 (10):2295 (1995).				
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	Ji et al., "How Effective is KRM-1648 in Treatment of Disseminated Mycobacterium Avium Complex Infections in Beige Mice?," <i>Antimicrobial Agents and Chemotherapy</i> 40(2):437 (1996).				
	Kelly et al., "Low-Dose Aerosol Infection Model for Testing Drugs for Efficacy Against Mycobacterium Tuberculosis," <i>Antimicrobial Agents and Chemotherapy</i> 40(12):2809 (1996).				
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	Lenaerts et al., "Evaluation of Rifalazil in a Combination Treatment Regimen as an Alternative to Isoniazid-Rifampin Therapy in a Mouse Tuberculosis Model," <i>Antimicrobial Agents and Chemotherapy</i> 44(11):3167 (2000).				
	Mae et al., "Effect of a New Rifamycin Derivative, Rifalazil, on Liver Microsomal Enzyme Induction in Rat and Dog," <i>Xenobiotica</i> 28(8):759 (1998).				
	Mae et al., "Isolation and Identification of Major Metabolites of Rifalazil in Mouse and Human," <i>Xenobiotica</i> 29:1073 (1999).				
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		OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION)	
		Roblin et al., "In Vitro Activities of Rifamycin Derivatives ABI-1648 (Rifazil, KRM-1648), ABI-1657, and ABI-1131 Against Chlamydia Trachomatis and Recent Clinical Isolates of Chlamydia Pneumoniae," <i>Antimicrobial Agents and Chemotherapy</i> 47:1135 (2003).	
		Saito et al., "Therapeutic Efficacy of Benzoxazinorifamycin, KRM-1648, Against Disseminated Mycobacterium Avium Infection Induced in Rabbits," <i>Abstracts of the General Meeting of the American Society for Microbiology</i> 93:174 (1993).	
		Sano et al., "Therapeutic Effects of Benzoxazinorifamycin KRM-1648 Administered Alone or in Combination with a Half-sized Secretory Leukocyte Protease Inhibitor or the Nonsteroidal Anti-inflammatory Drug Diclofenac Sodium against Mycobacterium Avium Complex Infection in Mice," <i>Antimicrobial Agents and Chemotherapy</i> 43(2):360 (1999).	
		Sato et al., "Antimicrobial Activities of Benzoxazinorifamycin KRM-1648, Clarithromycin and Levofloxacin Against Intracellular Mycobacterium Avium Complex Phagocytosed by Murine Peritoneal Macrophages," <i>Journal of Antimicrobial Chemotherapy</i> 41(1):77 (1998).	
Shimizu et al., "Effects of the Chinese Traditional Medicine Mao-bushi-saishin-to on Therapeutic Efficacy of a New Benzoxazinorifamycin, KRM-1648, Against Mycobacterium Avium Infection in Mice," <i>Antimicrobial Agents and Chemotherapy</i> 43(3):514 (1999).			
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Tomioka et al., "Intramacrophage Passage of Mycobacterium Tuberculosis and M. Avium Complex Alters the drug susceptibilities of the organisms as determined by intracellular Susceptibility Testing using Macrophages and Type II Alveolar Epithelial Cells," <i>Antimicrobial Agents and Chemotherapy</i> 46:519 (2002).			
Wallis et al., "Inhibition of Isoniazid-induced Expression of Mycobacterium Tuberculosis Antigen 85 in Sputum: Potential Surrogate Marker in Tuberculosis Chemotherapy Trials," <i>Antimicrobial Agents and Chemotherapy</i> 45(4):1302 (2001).			
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Yamamoto et al., "Activity of KRM-1648 Alone or in Combination with Both Ethambutol and Kanamycin or Clarithromycin Against Mycobacterium Intracellulare Infections in Beige Mice," <i>Antimicrobial Agents and Chemotherapy</i> 40(2):429 (1996).			
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